K002026

Section II 510(k) Summary and Certification

SEP - 6 2000

# CAPIOX® CX*AF200X Arterial Filter
## 510(k) Summary and Certification

**Submitter Information:**

Name and Address:
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton MD 21921

Contact Person: Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: May 25, 2000

**Device Names:**

Proprietary Name: CAPIOX® Arterial Filter
Product Code: CX*AF200X
Common Name: Arterial Line Blood Filter
Classification Name: Cardiopulmonary Bypass Arterial Line Blood Filter

**Predicate Device:**

Terumo Cardiovascular Systems Corporation has identified the Avecor Affinity™ Arterial Filter as the predicate device for the determination of substantial equivalence. The Avecor device is cleared with Premarket Notification K952532.

**Intended Use:**

The CAPIOX® CX*AF200X Arterial Filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours.

**Principles of Operation and Technology:**

The CAPIOX® CX*AF200X Arterial Filter performs its functions using two basic forms of technology. As a filtration device, non-biologic particulates in the blood stream are captured and removed from the blood flow as blood passes through the 37 μm filter mesh material that is contained within the device housing. The 37 μm filter mesh material establishes a physical barrier that entraps particulate matter and prevents it from moving downstream of the arterial filter assembly.

As an air-removal device, the CAPIOX® CX*AF200X Arterial Filter is designed so that air is removed from the blood stream as a result of centripetal force. The blood inlet port of the device is positioned on the side axis of the polycarbonate housing, thereby creating

a spiral blood flow pattern as blood enters the device. Because the blood flows through the device in a spiral motion, centripetal forces cause the air bubbles to migrate towards the top of the housing assembly. The top of the housing assembly is conical-shaped, thereby facilitating air movement towards the purge port located at the top of the assembly.

**Design and Materials:**
The design of the CAPIOX® CX*AF200X Arterial Filter is intended to remove non-biologic particulates while simultaneously facilitating the removal of air that might be in the blood flow. The blood-contacting surfaces of the device are coated with Terumo's polymer coating solution. The device accomplishes its intended use primarily due to its design characteristics.

The filter is comprised of an outer housing that contains a smaller inner housing. The outer housing is cylindrical in shape and has a conical-shaped lid assembly with an air vent port. The blood inlet port is positioned along the side axis of the outer housing and provides the entry point for blood. The base of the housing contains the blood outlet port.

The inner housing of the device contains a screen filter through which blood will pass through for filtration of particulate matter. After the blood has been filtered, it then exits the assembly via the blood outlet port.

The CAPIOX® CX*AF200X Arterial Filter also has a removable stopcock assembly attached to the air vent port to assist in the air removal process.

The materials of construction for the CAPIOX® CX*AF200X Arterial Filter are equivalent to the materials used in the Affinity™ Arterial Filter. The differences in the materials do not raise any new issues of safety or effectiveness of the device.

**Performance:**
Terumo Cardiovascular Systems Corporation conducted several evaluations of the CAPIOX® CX*AF200X Arterial Filter to demonstrate its equivalence to the Avecor Affinity™ Arterial Filter. Terumo conducted the following *in-vitro* performance tests to demonstrate equivalence:

- Filtration Efficiency
- Air Handling Capabilities
- Device Effect Upon Cellular Blood Components (cellular destruction)
- Pressure Drop (Short-term and 6-Hour)
- Mechanical Integrity
- Static Priming Volume
- Evaluation of the Connection of PVC Tubing to Inlet and Outlet Ports.

**Substantial Equivalence:**
The CAPIOX® CX*AF200X Arterial Filter is substantially equivalent to the Avecor Affinity™ Arterial Filter as follows:

- Intended Use: Both the CAPIOX® Arterial Filter and the Affinity™ Arterial Filter are intended to filtrate non-biologic particulates and emboli and to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours.

- Principles of Operation and Technology: The CAPIOX® Arterial Filter and the Affinity™ Arterial Filter each utilize the same technologies in the operation of the devices. Air removal is accomplished through spiral blood flow patterns that create centripetal force, thereby facilitating air movement towards the air vent port. Filtration is accomplished with a polyester screen material that prevents particulates from passing through the filter device.

  Design and Materials: The CAPIOX® Arterial Filter and the Affinity™ Arterial Filter each have the same basic design in they are each comprised of a screen mesh that is contained within a housing assembly. The screen is responsible for the removal of particulate matter while a spiral blood flow pattern facilitates air removal. Each device has a blood inlet port that provides for blood entry, and a blood outlet port that provides for blood exit from the device. Each device contains a standard luer port for the attachment of a stopcock assembly to assist in air removal. The materials used in the construction of the two devices are equivalent and do not create differences in the performance of the devices. Furthermore, the differences in the materials do not create any new issues of safety or effectiveness.

- Performance: Comparisons between the performance of the CAPIOX® Arterial Filter and the Affinity™ Arterial Filter were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the two devices.

**Substantial Equivalence Summary:**
In summary, the CAPIOX® Arterial Filter and the Affinity™ Arterial Filter are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

**Additional Safety Information:**

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo Cardiovascular Systems Corporation conducted the biocompatibility studies recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Terumo Cardiovascular Systems Corporation also conducted studies for materials characterization, including physico-chemical profiles and FT-IR scans.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

- Safety evaluations of the polymer coating were conducted by Terumo Corporation (Japan). Those studies include:

  - Acute Systemic Toxicity Testing (in Rats)
  - Genotoxicity Testing – Bacterial Reverse Mutation
  - Genotoxicity Testing – Chromosome Aberration
  - Sensitization (in Guinea Pigs)

- *In Vitro* studies using human blood were conducted to demonstrate the hemocompatiblity of the polymer coating.

**Conclusion:**

In summary, the CAPIOX® CX*AF200X Arterial Filter is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to Avecor's Affinity™ Arterial Filter (K952532).

**Terumo Cardiovascular Systems' statement that this device is substantially equivalent to any other device is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Terumo Medical Corporation
c/o Mr. Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K002026
Capiox® Arterial Filter
Regulatory Class: III (three)
Product Code: DTM
Dated: June 30, 2000
Received: July 3, 2000

Dear Mr. Courtney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

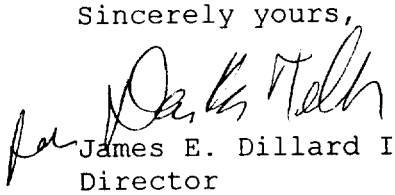
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648 Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Evaluation
Office of Device Evaluation
Center for Devices and
Radiological Health

**510(k) Number (if known):** K002026

**Device Name:** CAPIOX® Arterial Filter

**Indications For Use:**

Intended Use Described In The 510(k):

The CAPIOX® Arterial Filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through a cardiopulmonary bypass circuit for up to 6 hours.

The CAPIOX® Arterial Filter is coated with X-Coating, which is a polymer coating that is applied to blood contacting surfaces of the device to reduce the adhesion of platelets to the surfaces of the device.

Garry A. Courtney
Regulatory Affairs
Terumo Medical Corporation

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002026

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)